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CASE BP/G-33315A

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF Art Unit: 1646

STEMPFER ET AL.

APPLICATION NO: 10/568,332

FILED: FEBRUARY 13, 2006

FOR: PROCESS FOR THE PURIFICATION OF RECOMBINANT POLYPEPTIDES

MS: Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

SPECIES ELECTION WITH TRAVERSE

Sir:

Applicants submit the following response to the election requirement mailed April 3, 2008.

Applicants respectfully traverse the election requirement. According to the Patent Office, there is no unifying technical feature among the group 1 species *Escherichia coli*, *Pseudomonas sp.*, *Enterobacter sp.*, *Campylobacter sp.*, and *Vitreoscilla sp.*, because "each of the five bacteria has distinct properties and growing conditions." Election Requirement, page 3. On the contrary, the bacteria to be used in the present invention all share a very important unifying technical feature expressly recited in the claims – the presence of a periplasm. The inventive step of the claim processes does *not* lie in the particular fermentation conditions required by any particular prokaryotic cell having a periplasm, or involve any other property one could consider as creating a non-unifying distinction among them. Rather, the invention lies in the novel process of expressing a polypeptide of interest such that it is excreted into the periplasm of the host cell, followed by extraction of the polypeptide by osmotic shock. Thus, the present invention does not depend upon the use of any particular prokaryotic host cell having a periplasm, as all such cells are suitable for use in the invention.

The Patent Office also asserts that there is no unifying technical feature among group 2 species of an interferon, an interleukin, a growth hormone, a growth factor, a cytokine, an

enzyme, and enzyme inhibitor, and an antibody, because "each of the polypeptides of interest has a distinct structure and functional properties." However, the novel process of the present invention does *not* in any way depend upon particular structural properties or *in vivo* function of the expressed polypeptide of interest – the invention is a process for producing the polypeptide, not a process for its use. Thus the structural and functional properties of the particular polypeptide of interest are not critical to, nor indeed have any particular impact on, the operation of the claimed invention. The ability to produce a variety of polypeptides using the claimed process is in fact a major benefit of the present invention, and does not create a lack of unity of invention among the claims.

In view of the foregoing, Applicants believe that this election requirement is unnecessary. However, because a full response, even with traverse, requires an election of species and identification of all claims encompassing the elected species (Election Requirement, page 3, Applicants hereby elect, with traverse, the species (a) *Escherichia coli* from species group 1, and (a) an interferon from species group 2. Claim 1 is generic for both species group 1 and group 2, and claim 10 is generic for species group 2. Claims 1-23 encompass species group 1 – the processes encompassed by each of these claims can be practiced using *E. coli* as the prokaryotic host cell; claims 1-23 encompass species group 2 – an interferon can be the polypeptide on interest in the processes encompassed by each of these claims.

CONCLUSION

Reconsideration and withdrawal of the election requirement is respectfully requested, and favorable action on the claims is earnestly solicited.

Respectfully submitted,

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